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09/397,782

09/16/1999

CHARLES A. CONRAD

INGA.004/CIP

9185

7590

05/26/2006

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EXAMINER

MARTINELL, JAMES

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/397,782

Applicant(s)

CONRAD, CHARLES A.

Examiner

James Martinell

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1634

The drawings are objected to for the reasons given in the Notice of Formal Drawings Required mailed December 19, 2000. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The disclosure is objected to because of the following informalities.

- (a) The instant application does not comply with the Sequence Rules (37 CFR §§ 1.821-1.825) in that Table I does not recite SEQ ID NOs as required (see 37 CFR § 1.821(d) and MPEP 2422. Applicant's statement that SEQ ID NOs were provided in the machine readable and paper copies of the Sequence Listing (see the response filed July 14, 2005, page 2) does not address the lack of SEQ ID NOs in the Table itself. Any response to this Office action, in order to be considered a complete response, must correct this deficiency.
- (b) Figures 2 and 3 contain biological sequences without SEQ ID NOs as identifiers as is required under 37 CFR § 1.821(d) and MPEP 2422. Any response to this Office action, in order to be considered a complete response, must correct this deficiency.

Appropriate correction is required.

Art Unit: 1634

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by any one of Mirochnitchenko et al (J. Biol. Chem. 269: 2380 (1994)), Miyata et al (EP 0 532 380), or Inouye et al (EP 0 562 206). Each of the references discloses vectors for the *in vivo* production of single stranded antisense DNA utilizing a vector that contains a template for antisense DNA flanked by the inverted repeats and employing a cloned RT gene for production of reverse transcriptase and thus, single stranded DNA. For example, see Mirochnitchenko et al "Results and Discussion" section, Miyata et al, pages 4-10, and Inouye et al, pages 5-14. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed June 15, 2001, page 3, first full paragraph). Applicant's assertion (response filed July 14, 2005, page 2) is not convincing. Each of the cited regions of the references discloses all of the elements that are required in the claims. For example, msDNAs necessarily contain tandem repeats because they form stable stem-loop structures (*e.g.*, see Inouye et al at page 5, lines 30-49). In addition, a primer binding site may be broadly interpreted as any stretch of nucleic acid since any small piece of nucleic acid may be used as a primer. That ssDNA is produced is evident in the titles of each of the references. Applicant's arguments are not commensurate with the breadth of the claims. The claims are considerably broader than what is described in the application. For example, see page 6, lines 4-21 and page 11, lines 10-29.

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Miyata et al (U.S. Patent No. 5,436,141). The reference discloses vectors for the *in vivo* production of single stranded antisense DNA utilizing a vector that contains a template for antisense DNA flanked by the inverted repeats and employing a cloned RT gene for production of reverse transcriptase and thus, single stranded DNA. For example, see columns 5-14 and claims 1-45. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed June 15, 2001, page 3, second full paragraph). Applicant's assertion (response filed July 14, 2005, page 2) is not convincing. Each of the cited regions of the reference discloses all of the elements that are required in the claims. For example, msDNAs necessarily contain tandem repeats because they form stable stem-loop structures (*e.g.*, see column 6, lines 11-28). In

Art Unit: 1634

addition, a primer binding site may be broadly interpreted as any stretch of nucleic acid since any small piece of nucleic acid may be used as a primer. That ssDNA is produced is evident in the titles of each of the references. Applicant's arguments are not commensurate with the breadth of the claims. The claims are considerably broader than what is described in the application. For example, see page 6, lines 4-21 and page 11, lines 10-29.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Art Unit: 1634

**OFFICIAL FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1634**

5/18/06